

REMARKS

Claim Amendments and the Rejections under 35 USC §§ 101 and 112

All the formality rejections are overcome by the amendments to the claims.

Dependent claims are also added which find support in the specification.

The claims further clarify that the adhesive is "a non-radioactive and non-pharmacophor-containing adhesive." Support for these features of the adhesive can be found, for example, on page 5, line 17-18, (distinguishing between adhesive and adhesive radioactive isotope), on page 7, line 18, (describing a non-activated peptide as an adhesive), page 8, lines 1-21, (describing two embodiments where a lipophilic compound is used as adhesive which is activated after being coated onto the stent surface), and on page 8, last two lines to page 10, line 10, (describing several embodiments wherein gold is used as the adhesive which is activated after its use as an adhesive). Further support can be found in the numerous examples of the specification.

Additionally, applicants bring the attention of the examiner to MPEP § 2173.05(i), titled "Negative Limitations," stating "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support," citing *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1993). Additionally, please see *In re Herschler*, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); *In re Edwards*, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978); *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), (adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention,) and *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973)," (it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed.) Applicants have clearly conveyed to one having ordinary skill in the art that applicants had possession of "a non-radioactive and non-pharmacophor adhesive." One of ordinary skill in the art clearly would understand based on the disclosure that the claimed adhesives are non-radioactive and non-pharmacophor adhesives. Additionally, even without consulting the specification, one of ordinary skill in the art, unless specifically being instructed otherwise, would understand the term "adhesive" to refer to an adhesive that does not have radioactive or pharmacophor properties. A radioactive or pharmacophor adhesive would be the exception to the rule.

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Additionally, if alternative elements are positively recited in the specification, they may

be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977), and MPEP § 2173.05(i). Applicants in the specification describe in positive terms embodiments of the adhesives being non-activated as well as activated. See discussion above. Thus, the exclusion of non-activated embodiments is proper under *Johnson*.

The Rejections Under 35 USC §§ 102 and 103

Claim 18 is rejected under section 102 as allegedly anticipated by Fischell et al.

Fischell et al. teaches a stent that has a single coating that has both antithrombogenic and radioactive properties, see column 1, lines 29-31, lines 43-44, and lines 61-63, and a stent having two layers, an inner layer which is both antithrombogenic and radioactive, and an outer layer which is only antithrombogenic, see column 1, lines 32-41, lines 45-47, and column 2, lines 1-3. It is clear from the disclosure of Fischell et al. that the antithrombogenic agent, i.e., phosphorychlorine coating, see column 1, lines 14-15 and 34-41, is different from the radioisotope. None of these embodiments anticipate or even render obvious a stent that is coated by a non-radioactive and non-pharmacophor-containing adhesive that has been activated by a radioactive isotope after coating the stent with said adhesive.

Claim 15 is rejected under section 103 as allegedly unpatentable over Fischell et al.

Fischell et al. is discussed above and the discussion is incorporated herein as well.

None of the embodiments described by Fischell et al. render obvious a process for preparing a stent that is coated by a non-radioactive and non-pharmacophor adhesive that has been activated by a radioactive isotope prior to coating the stent with said adhesive.

Claim 18 is rejected under section 102 as allegedly anticipated by, and claim 16 is rejected under section 103 as allegedly unpatentable over Armini et al.

Applicants note that Armini et al. has a US priority of July 7, 1997, while all the priority documents of the present application are dated April 30, 1997, or June 3, 1997, i.e., predate the

reference. A certified copy of the priority documents will be sent as soon as they will become available.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Csaba Henter, Reg. No. 50,908

Anthony J. Zelano, Reg. No. 27,969

Attorneys/Agents for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.

Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410
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Version With Markings To Show Changes Made

In the Claims

The claims have been amended as follows:

15. (Amended) A process for preparing a radioactive stent comprising reacting Process
~~for the production of radioactive stents, wherein a radioactive isotope is reacted with an a non-~~
radioactive and non-pharmacophor-containing adhesive at 0-100°C, and followed by coating the
~~stent is then coated with the radiolabeled adhesive at 0°C-100°C.~~

16. (Amended) A process for preparing a radioactive stent comprising coating Process
~~for the production of radioactive stents, wherein a non-radioactive stent is coated with the a non-~~
radioactive and non-pharmacophor-containing adhesive at 0°C-100°C, followed by coating the
stent with a radioactive isotope by placing the stent and then is mixed at 0-100°C with into a
solution of the radioactive isotope.

18. (Amended) ~~Use of stents that consist of stent parent substances, adhesives and a~~
~~radioactive isotope for the production of an implant~~ A method ~~for prophylaxis of restenoses~~
restenosis comprising implanting a non-radioactive stent that has been coated with a non-
radioactive and non-pharmacophor-containing adhesive followed by being activated by a
radioactive isotope.

Claims 28 to 45 have been newly added.